K020804

## IX. 510(k) Summary of Safety and Effectiveness

NOV 1 9 2002

| | |
|---|---|
| SUBMITTER: | United States Surgical<br>150 Glover Avenue<br>Norwalk, CT 06856 |
| CONTACT PERSON: | Sarah Hubeny |
| DATE PREPARED: | March 8, 2002 |
| CLASSIFICATION NAME: | Staple, Implantable |
| COMMON NAME: | Staple, Implantable |
| PROPRIETARY NAME: | Auto Suture* PREMIUM PLUS CEEA*<br>Disposable Stapler |
| DEVICE DESCRIPTION: | The Auto Suture* PREMIUM PLUS CEEA* Disposable Stapler is a single patient use device which places a double staggered row of titanium staples. Immediately after staple formation, the instrument's knife blade resects the excess tissue, creating a circular anastomosis. |
| INTENDED USE: | The Auto Suture* Premium Plus CEEA* Disposable Stapler has application throughout the anal canal to perform surgical treatment of hemorrhoidal disease. |
| MATERIALS: | All component materials of the Auto Suture* Premium Plus CEEA* Disposable Stapler are comprised of materials which are in accordance with ISO Standard #10993-1. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 9 2002

United States Surgical
Sarah Hubeny
Regulatory Affairs Associate
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K020804
Trade/Device Name: Auto Suture PREMIUM PLUS CEEA Disposable Stapler
Regulation Number: 872.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: September 19, 2002
Received: September 19, 2002

Dear Ms. Hubeny:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Hunt

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K020804

**IV. Indications For Use:**

510(k) Number (if known): _____

Name: Auto Suture* PREMIUM PLUS CEEA* Disposable Stapler

Indications For Use:

The Auto Suture* Premium Plus CEEA* Disposable Stapler has application throughout the anal canal to perform surgical treatment of hemorrhoidal disease.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use: _____ OR Over-The-Counter Use: _____
(Per 21 CFR §801.109)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020804